Citation:

Albertson AM, Affenito SG, Bauserman R, Holschuh NM, Eldridge AL, Barton BA. The relationship of ready-to-eat cereal consumption to nutrient intake, blood lipids, and body mass index of children as they age through adolescence. *J Am Diet Assoc.* 2009 Sep;109(9):1557-65.

PubMed ID: 19699835

Study Design:

Randomized Controlled Trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To report observational analyses of the relationship between ready to eat (RTE) cereal consumption and outcome measurements of nutrient intake, blood lipid levels, and body mass index (BMI) from the randomized longitudinal clinical dietary intervention trial, the Dietary Intervention Study in Children (DISC).

Inclusion Criteria:

Data reviewed from the DISC data included participants who received dietary intervention and those who did not (controls). The original DISC study was conducted from 1987-1990 and was extended to 1996. This study utilizes data from participants, aged 8-10 years at baseline, who had complete data for height, weight, dietary records, physical activity assessment, pubertal maturation and blood lipids.

Exclusion Criteria:

- DISC participants with incomplete data were excluded.
- Children who were not pre-pubertal at baseline or had mean serum low density lipoprotein (LDL) cholesterol levels less than the 80th percentile or greater than the 98th percentile for their sex and age were also excluded.

Description of Study Protocol:

Recruitment

Complete data sets for children aged 8-10 years at baseline of the DISC dietary intervention study.

Design: Secondary analysis of the DISC study, a randomized controlled clinical trial.

Blinding used not specified

Intervention

DISC study included intensive education and diet interventions and was assessed on an intent-to-treat design, children were randomized to a total fat- and saturated fat-modified dietary intervention or usual care.

Statistical Analysis

- Used SAS version 9.1.3, 2002-2003, SAS Institute Inc, Cary, NC
- Trend analysis and model development with repeated measures mixed models and z scores

Data Collection Summary:

Timing of Measurements

Baseline, 1 year, 3 years, 5 years, 7.5 years.

Dependent Variables

- Total energy intake (calories)
- Macronutrients [energy from protein, fats, saturated fats, monounsaturated fats, polyunsaturated fats, and carbohydrates and sucrose (grams), fiber (grams), and cholesterol (milligrams)]
- Micronutrients [vitamin C (mg), vitamin D (µg), folate (µg), calcium (mg), iron, (mg), zinc (mg), sodium (mg)]
- Total serum cholesterol (mg/dL)
- High density lipoproteins (HDL, mg/dL)
- Low density lipoproteins (LDL, mg/dL)
- Very low density lipoproteins (VLDL, mg/dL)
- Triglycerides (mg/dL)
- Body mass index (BMI, kg/m^2)

Independent Variables

- DISC study included intensive education and diet interventions, children were randomized to a total fat- and saturated fat-modified dietary intervention or usual care
- RTE cereal consumption (days)
- Dietary intake measured with five sets of three 24-hour recalls

Control Variables

- Age
- Sex

Description of Actual Data Sample:

Initial N: 663 (361 boys, 299 girls, 87% White)

Attrition (final N): 650 (354 boys, 296 girls) due to complete data available

Age: Baseline boys 9.8 years, girls, 9.1 years

Ethnicity: 87% white

Other relevant demographics: not specified

Anthropometrics Groups were similar at baseline.

Location: USA, multicenter sites in DISC study conducted by the National Heart Lung and Blood Institute, National Institutes of Health, Bethesda, MD

Summary of Results:

Key Findings

- Ready to eat (RTE) cereal consumption and breakfast consumption declined steadily with age in both boys and girls. Declines in RTE cereal were larger than those in breakfast overall.
- Boys consumed RTE cereal more often than girls (year 5, p=0.003) and in larger portions (24%, 1.38 c vs 1.11 c, p<0.0001) but girls consumed breakfast more frequently.
- Total energy intake was not related to RTE cereal consumption for either boys (p=0.50) or girls (p=0.12).
- RTE cereal consumption was associated with higher fiber intake and higher sucrose intake and with reduced intake of cholesterol.
- Micronutrient intake was significantly associated with RTE cereal.
- Boys who ate RTE cereal more often had lower total serum cholesterol (p=0.019), lower LDL cholesterol (p=0.048) and lower BMI (p=0.020).

Author Conclusion:

Greater frequency of RTE cereal consumption was associated with higher fiber intake, higher micronutrient intake (vitamins C and D, folate, calcium, iron and zinc), higher percentage of energy from carbohydrate and higher sucrose intake with reduced intake of cholesterol and lower percentage of energy from total and all types of fats.

"Consistent RTE cereal consumption contributes to a healthful dietary pattern and nutrient intake that is favorably associated with CVD risk factors such as lipid levels and BMI, particularly among boys."

Reviewer Comments:

Strengths: large subject pool with good retention rates in highly defined study and data collection

Weaknesses: potential bias due to funding (cereal company) - authors note limited generalizability because of the homogenous composition of the study population.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	???
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A

3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	Yes
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	N/A
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	Yes
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	Yes
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes

6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	No
6.6.	Were extra or unplanned treatments described?	No
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	Yes
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes

9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	No
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	No